



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	1E15.20
True Name	Equine Rotavirus Vaccine, Killed Virus
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Duvaxyn R - No distributor specified
Date of Compilation Summary	April 23, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Safety
Pertaining to	All
Study Purpose	Evaluate safety under typical field conditions
Product Administration	Three intramuscular doses at 28-30 days apart during final three months of pregnancy
Study Animals	Pregnant mares at least 2 years of age in last trimester of pregnancy
Challenge Description	
Interval observed after challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	October 26, 1995